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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,380	02/08/2002	Li-Lan H. Chen	366325-503	1761

25561 7590 09/24/2003

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EXAMINER	
BENNETT, RACHEL M	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,380	CHEN ET AL.	
	Examiner	Art Unit	
	Rachel M. Bennett	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *6-9, 17-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 10-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The examiner acknowledges receipt of the IDS filed 5/9/03.

Election/Restrictions

1. Applicant's election without traverse of Group I and elected species famotadine in Paper No. 8 is acknowledged. Claims 1-5, 10-16 read on the elected species.

Specification

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-5, 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zyck et al. (US 6541048).

Applicants claims a composition comprising a pharmaceutically acceptable carrier and an active agent complexed with glycyrrhizin wherein the active agent contains at least one nitrogen-containing moiety; and wherein the composition is substantially free of uncomplexed active agent.

Zyck discloses a coated chewing gum product comprising a chewing gum core and a coating on the core, the coating comprising an acid blocker. Famotidine is the preferred acid blocker. A coating syrup comprises a bulk sweetener. See col. 2 lines 18-65. The dosage level of acid blocker used in a preferred coated chewing gum product will vary depending on the acid blocker used. For example, the coated chewing gum will provide 10 mg of famotindine. See

col. 4 lines 6-19. High intensity sweeteners are preferably added to the coating containing calcium carbonate to give a high quality, consumer-acceptable product. See col. 4 lines 51-65. Preferred sweeteners include glycyrrhizin. See col. 7 lines 47-60. Claims 1-30 disclose a chewing gum product comprising famotdine and glycyrrhizin. Zyck does not disclose the mole ratio of glycyrrhiznic acid to active agent to be 1:1 to 1:3.

Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined the ratio of glycyrrhizinic acid to the active agent because Zyck discloses the dosage level of acid blocker used in a preferred coated chewing gum product will vary depending on the acid blocker used. Therefore, one of ordinary skill in the art, through routine experimentation, would determine a suitable ratio in order to provide a high quality, consumer-acceptable product as taught by Zyck.

4. Claims 1-5, 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. (US 5576014).

Applicants claims a composition comprising a pharmaceutically acceptable carrier and an active agent complexed with glycyrrhizin wherein the active agent contains at least one nitrogen-containing moiety; and wherein the composition is substantially free of uncomplexed active agent.

Mizumoto et al. disclose intrabuccally dissolving compressed moldings comprising a saccharide having a low moldability having been granulated with a saccharide having high moldability. See abstract. Preferable active ingredients used are famotidine, tamsulosin hydrochloride, and YM 934. Preferably, the active ingredient may be used in an amount of 50% (w/w) or less, preferably 20% (w/w) or less based on the total solid components, though it varies

depending on the nature of each active ingredient. See col. 10, lines 14-29. Additive agents include artificial sweeteners such as glycyrrhizin dipotassium. See col. 13, lines 36-49. Mizumoto does not disclose the mole ratio of glycyrrhiznic acid to active agent to be 1:1 to 1:3.

Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined the ratio of glycyrrhizinic acid to the active agent because Mizumoto discloses the the active ingredient may be used in an amount of 50% (w/w) or less, preferably 20% (w/w) or less based on the total solid components, though it varies depending on the nature of each active ingredient. Therefore, one of ordinary skill in the art, through routine experimentation, would determine a suitable ratio in order to provide a intrabuccally dissolving compressed molding as taught by Mizumoto.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

rmb

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600